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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,927	02/19/2002	Thomas Curran	SJ-01-0032	6357

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ST. JUDE CHILDREN'S RESEARCH HOSPITAL
OFFICE OF TECHNOLOGY LICENSING
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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/078,927	Applicant(s) CURRAN ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10,11,13-15,32 and 35 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,10,11,13-15,32 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] The finality of the rejection of the last Office action is withdrawn. The instant Office action is non-final.
- [2] Claims 1, 4-8, 10-11, 13-15, 32, and 35 are pending in the application.
- [3] Applicant's after-final amendment to the claims, filed on 4/6/2006, is acknowledged and has been entered into the record. This listing of the claims replaces all prior versions and listings of the claims.
- [4] Applicant's amendment to the specification, filed on 4/6/2006, is acknowledged.
- [5] Applicant's arguments filed on 4/6/2006 in response to the Office action mailed on 2/21/2006 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

- [7] The amendment filed on 4/25/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the nucleic acid

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sequences of SEQ ID NO:4 and 5 in the sequence listing paper copy filed on 11/21/2005 and reference thereto in the specification amendment to pp. 3 and 22 filed on 11/21/2005. The examiner acknowledges reference to non-patent literature GenBank Accession Numbers 3288851 and 1771281 in the specification at p. 4, lines 24-25 of the specification. Furthermore, the examiner acknowledges previous remarks in the Office action mailed on 8/22/2005, wherein the examiner stated, "...the sequence of a disclosed GenBank Accession Number in the specification is considered to be an inherent 'incorporation by reference'..."

According to MPEP § 608.01(p), incorporation by reference of material in a non-patent document "must be set forth in the specification and must: (1) Express a clear intent to incorporate by reference by using the root words "incorporat(e)" and "reference" (e.g., "incorporate by reference"); and (2) Clearly identify the referenced patent, application, or publication." See 37 § 1.57(b). MPEP § 608.01(p) further states, "[i]f a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended."

It is noted that there is no clear intent to incorporate by reference the sequences of GenBank Accession Numbers 3288851 and 1771281 using the root words "incorporat(e)" and "reference" (e.g., "incorporate by reference"). Thus, according to MPEP § 608.01(p), "examination will proceed as if no incorporation by reference statement has been made." As such, upon reconsideration of the incorporation of the

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sequences of GenBank Accession Numbers 3288851 and 1771281 into the specification, the examiner considers the sequences of SEQ ID NO:4 and 5 to be new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, First Paragraph

[8] The indicated allowability of claim 32 is withdrawn in view of the new rejection set forth below.

[9] Claims 1, 4-8, 10-11, 13-15, 32, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection that is necessitated by amendment.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

Claim 1 (claims 4-8, 10-11, and 13-15 dependent therefrom), 32, and 35 recite the limitation(s) "SEQ ID NO:4" and/or "SEQ ID NO:5." MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new

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or amended claims” and “[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description.” As a showing of support for the sequence of SEQ ID NO:4, applicant asserts “[s]upport for incorporation of SEQ ID NO:4 in the specification can be found on page 4, lines 22-24, which identifies the genbank accession number of murine dab1” and that “SEQ ID NO:4 was extracted from the sequence information referenced under this genbank accession number” (response filed on 4/25/2005 at p. 8, bottom). As a showing of support for the sequence of SEQ ID NO:5, applicant asserts “[s]upport for including SEQ ID NO:5 can be found on p. 4 beginning on line 22 identifying the genbank number 3288851, which lists the human dab1 nucleotide sequence” (response filed on 11/21/2005 at p. 5, middle). However, as noted above, the material disclosed by GenBank Accession Numbers 1771281 and 3288851 is not properly incorporated by reference. As such, reference to the sequences of SEQ ID NO:4 and 5 in the claims is considered to be new matter.

Conclusion

[10] Status of the claims:

Claims 1, 4-8, 10-11, 13-15, 32, and 35 are pending.

Claims 1, 4-8, 10-11, 13-15, 32, and 35 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-

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272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
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